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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/992,211	11/16/2001	Peter M. Bonutti	BON-2950-2	7013
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33771 7590 02/25/2003

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MIAMI, FL 33131

EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/992,211

Applicant(s)
Bonutti et al.

Examiner
Michael Thaler

Art Unit
3731



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 3, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-62, 64-73, 75, and 77-79 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57-62, 64, 65, 72, 73, 75, and 77-79 is/are allowed.
- 6) ☒ Claim(s) 66, 70, and 71 is/are rejected.
- 7) ☒ Claim(s) 67-69 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15 6) ☐ Other:

Art Unit: 3731

Claims 66 and 70 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fogarty et al. (5,234,425). Fogarty et al. show tubular sheath 40 and filaments 42 which are inherently resiliently expandable. Although the described intended use of the sheath 40 is radially contracting it from its figure 2 relaxed configuration, an expanding force applied to it (by a dilator inserted within it, for example) would expand it since sheath 40 is made of resilient material. When the expanding force is removed, the sheath would inherently return to its relaxed configuration since it is made of resilient material. Thus, when used in this manner, the sheath would be biased in the contracted position (shown in figure 2). Alternatively, the sheath 40 and filaments 42 are obviously resiliently expandable since sheath 40 is made of resilient material. As to claim 70, the Fogarty et al. sheath is inherently engageable by a member having an oval cross-section and is inherently expandable by inserting this member therein. The member having an oval cross-section is not part of the claimed combination.

Claims 66 and 71 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Andersen et al. (4,706,670). Andersen et al. show an expandable cannula (the catheter is broadly a "cannula" since it includes a central passageway 42 which receives guidewire 2)

Art Unit: 3731

comprising tubular sheath (the outer tubing of shaft 4) which is resiliently expandable (col. 2, lines 19-20) and filaments (col. 5, lines 7-15), wherein the sheath is biased in the contracted position shown in figure 4b (since it is made of elastic material). Alternatively, the Andersen et al. catheter is obviously a "cannula" since it includes a central passageway 42 which receives guidewire 2. As to claim 71, Andersen et al. show a passage (the inflation passage between the catheter shaft 4 and inner tube 26 described in col. 5, lines 35-38) which extends between opposite end portions of the sheath and pump means (the syringe 16 or other inflation device described in col. 3, lines 65-68).

Claims 57-62, 64, 65, 72, 73, 75 and 77-79 are allowed.

Claims 67-69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed Feb. 3, 2003 have been fully considered but they are not persuasive for the reasons set forth above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3731

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Application/Control Number: 09/992,211

Page 5

Art Unit: 3731

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
February 24, 2003



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731